

### **REMARKS**

Claims 1, 4-9, 21, and 23-60 are pending and under consideration, prior to Amendment. Claims 4 and 6-9 are withdrawn from consideration as directed to an unelected species. Applicants cancel, without prejudice, previously withdrawn claim 7. Applicant reserve the right to prosecute claims of similar or differing scope.

Applicants add new claims 61-67. Support for the subject matter of the newly added claims is found throughout the specification. No new matter has been added. Exemplary support can be found in paragraphs [0023], [0055], [0061], [0062], [0066], and [0715]-[0717] of the published specification.

Claim 60 has been amended to more particularly point out that the *colon cancer tissue overexpresses a gli-1 gene*. Support for Applicants' amendment can be found, for example, in paragraphs [0023] and [0066] of the published specification. No new matter has been entered.

Claims 4 and 6 have been withdrawn from consideration as elected to a non-elected species. However, Applicants have amended the withdrawn claims to correct claim dependency (e.g., so the withdrawn claims do not depend from a cancelled claim).

Applicants request entry of Applicants' after-final amendment. Applicants' amendments either place this case in condition for allowance or simplify issues for Appeal. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

### **Status of Application, Amendments and/or Claims**

Applicants note with appreciation that the amendment of December 13, 2007 has been entered in full.

### **Withdrawn Objections and/or Rejections**

Applicants note with appreciation the withdrawal of certain objections and rejections.

Applicants note that the rejection of claims 1, 5, 21, and 23-25 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims and Applicants' persuasive arguments.

Applicants note that the rejection of claims 1, 5, 21, and 23-25 under the judicially created doctrine of obviousness type double patenting has been withdrawn.

Applicants note that the rejection of claim 21 under 35 U.S.C. 112, second paragraph, has been withdrawn.

Applicants note that the rejection of claim 1 under 35 U.S.C. 102(b) as allegedly anticipated by Wallace et al. has been withdrawn.

Applicants note that the rejection of claim 1 under 35 U.S.C. 103(a) as allegedly unpatentable over Dahmane et al. #1 (1997) in view of Dahmane et al. #2 (1999) has been withdrawn.

### **New Rejections**

#### **Claim Rejections – 35 § USC 112, 1<sup>st</sup> paragraph, enablement**

Claim 60 is rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the enablement requirement. Applicants traverse this rejection and contend that the rejection is moot in view of the amended claims.

The basis of the rejection is that the specification allegedly fails to enable a method for treating colon cancers that do not over express the gli-1 or Sonic hedgehog gene. Applicants respectfully disagree. Nevertheless, to expedite prosecution, Applicants have amended claim 60 to more particularly point out that the colon cancer tissue overexpresses a *gli-1* gene. Applicants' amendment is not in acquiescence to the rejection. Applicants expressly reserve the right to prosecute claims of similar or differing scope.

Applicants note that on pages 4-5 of the Office Action, the Examiner details the extensive guidance provided in the specification regarding methods for treating various cancers that overexpress gli-1 or Sonic hedgehog. Although Applicants maintain that the specification enables an even more extensive range of treatment methods, including methods for treating tumors generally and regardless of whether they overexpress gli-1 or Sonic hedgehog, Applicants note that the amendment to claim 60, as well as newly added claims 61-67, are consistent with the subject matter indicated by the Examiner as enabled. Accordingly, reconsideration and withdrawal of this rejection are requested.

### **Double Patenting**

Claims 1, 5, 21, and 23-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 5 of copending application number 10/652,298. Applicants contend that the claims, as amended, in the instant and co-pending applications are patentable in view of each other. Nevertheless, Applicants ask that this rejection be held in abeyance until indication of allowable subject matter. Applicants will submit a terminal disclaimer, if necessary, upon indication of allowable subject matter.

Applicants note that, in accordance with MPEP 804.I.B., the Examiner will maintain the provisional double patenting rejection until there are either no longer any conflicting claims or the double patenting rejection is the only remaining rejection in at least one of the applications.

### **Co-Pending Applications**

The Examiner is obviously aware of co-pending application 10/652,298 (currently applied in the above noted double patenting rejection). Applicants direct the Examiner to the prior and ongoing prosecution of co-pending application 10/652,298 (most recent action is a Final Office Action mailed April 4, 2008). Additionally, Applicants take this opportunity to update the Examiner on the status of various co-pending applications – the existence of which has already been brought to the Examiner's attention and made of record in this case. The most recent action in application serial number 09/804,490 is a Notice of Allowance mailed April 18, 2008. The most recent action in application serial number 10/652,686 is a Final Office Action mailed April 30, 2008. The most recent action in application serial number 09/883,848 is a Final Office Action mailed March 3, 2008). The most recent action in application serial number 10/772,090 is an Advisory Action mailed May 19, 2008 (responsive to an after-final response mailed April 8, 2008). The most recent action in application serial number 10/727,195 is an Advisory Action mailed May 12, 2008 (responsive to an after-final response mailed February 28, 2008).

### **Supplemental IDS**

Applicants provide herewith a Supplemental Information Disclosure Statement.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945** under order number CIBT-P01-104.

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Respectfully submitted,

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